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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,809	05/01/2001	Olga Bandman	PF-0358-2 DIV	7331

27904            7590            03/11/2003  
INCYTE GENOMICS, INC.  
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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER

1653  
DATE MAILED: 03/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/847,809	BANDMAN ET AL.
	Examiner Karen Cochrane Carlson, Ph.D.	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 November 2002.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 10 and 29-44 is/are pending in the application.  
 4a) Of the above claim(s) 29,32,34,35 and 38 is/are withdrawn from consideration. *y344*

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 10,30,31,33,36,37 and 39-42 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> .	6) <input type="checkbox"/> Other: _____

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Applicant's election with traverse of RCN8 Invention IV, drawn to antibodies against RCN8 having SEQ ID NO: 3, Claims 10, 30, 31, 33, 36, 37, and 39-42 in Paper No. 7, filed November 12, 2002, is acknowledged. The traversal is on the ground(s) that methods of using this antibody should be rejoined when the antibody product is allowed. This is found persuasive because; however, the antibody is not allowable for reasons being made of record below and therefore the inventions will remain separate.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 11-28, and 45-48 have been canceled. Claims 29, 32, 34, 35, 38 have been withdrawn from further consideration at this time by the Examiner because these Claims are drawn to non-elected inventions. Claims 10, 30, 31, 33, 36, 37, and 39-42 are currently under examination.

Priority is to August 8, 1997.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36 and 39 depend from non-elected inventions. Therefore, these claims are indefinite.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 30, 31, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 recites that the antibody will specifically bind to a polypeptide having 90% identity to SEQ ID NO: 3, to biologically active fragments of SEQ ID NO: 3, and to immunogenic fragments of SEQ ID NO: 3. The specification does not teach polypeptides that meet these claim limitations, that is, the specification fails to describe active polypeptides having 90% identity to SEQ ID NO: 3, that comprise biologically active fragments of SEQ ID NO: 3, and comprise immunogenic fragments of SEQ ID NO: 3. Therefore, one skilled in the art cannot know what part of SEQ ID NO: 3 the antibody claimed specifically binds to because the specification lacks written description of these polypeptides.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 10, 30, 31, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Yabe et al. (July 18, 1997; J. Biol. Chem. 272:18323-18239) teach calumenin having 98.2% identity to SEQ ID NO: 3. On page 18234, col. 1, para. 3, Yabe et al. made antibodies against calumenin, anti-protein-disulfide isomerase antibody. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between RCN $\delta$  and calumenin is high, the antibody made by Yabe et al. will also bind polypeptides having SEQ ID NO: 3, 90% identity to SEQ ID NO: 3, biologically active fragments of SEQ ID NO: 3, and immunogenic fragments of SEQ ID NO: 3 (Claim 10, 30, 36, 39). At page 18234, col. 1, para. 3, the antibodies were in composition (Claim 31, 37, 40). The antibodies were labeled via conjugation with fluorescein isothiocyanate (Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

Claims 10, 30, 31, 33, 36, 37, and 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Ozawa et al. (1993; J. Biol. Chem. 268:699-705). Ozawa et al. teach reticulocalbin having 89.1% identity to SEQ ID NO: 3. See the alignment attached to the reference. On page 700, col. 2, para. 3, Ozawa et al. made antibodies against reticulocalbin. Given that antibodies bind epitopic structures rather than sequences per se, and the identity between RCN $\delta$  and reticulocalbin is high, the antibody made by Ozawa et al. will also bind polypeptides having SEQ ID NO: 3, 90% identity to SEQ ID NO: 3, biologically active fragments of SEQ ID NO: 3, and immunogenic fragments of SEQ ID NO: 3 (Claim 10, 30, 36, 39). At page 700, col. 1, para. 4, the antibodies were in composition (Claim 31, 37, 40). At page 700, col. 2, para. , the antibodies were labeled via conjugation with fluorescein isothiocyanate (Claim 33). Claims 41 and 42 are being considered to be anticipated as well because there appears to be no difference in the antibody made by a Fab expression library or and immunoglobulin expression library.

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No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

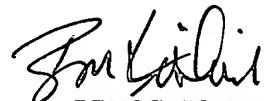
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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March 6, 2003



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER



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